



## General

### Guideline Title

American Osteopathic Association guidelines for osteopathic manipulative treatment (OMT) for patients with low back pain.

### Bibliographic Source(s)

Task Force on the Low Back Pain Clinical Practice Guidelines. American Osteopathic Association guidelines for osteopathic manipulative treatment (OMT) for patients with low back pain. J Am Osteopath Assoc. 2016 Aug;116(8):536-49. [36 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Osteopathic Association. American Osteopathic Association guidelines for osteopathic manipulative treatment (OMT) for patients with low back pain. Chicago (IL): American Osteopathic Association; 2009 Jul. 24 p. [61 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

Definitions for the levels of evidence (1a–5) are provided at the end of the "Major Recommendations" field.

The American Osteopathic Association recommends that osteopathic physicians use osteopathic manipulative treatment (OMT) in the care of patients with low back pain. Evidence from systematic reviews and meta-analyses of randomized clinical trials (Evidence Level 1a) supports this recommendation.

#### Definitions

Levels of Evidence

Strength of Evidence	Type of Study	Comment

Strength of Evidence	Type of Study	Comment
1a	Systematic review with homogeneity of randomized controlled trials	Individual trials should be free of substantial variations in the directions and magnitudes of results
1b	Individual randomized controlled trial with narrow confidence interval	Confidence interval should indicate a clinically important osteopathic manipulative treatment (OMT) effect
1c	Differential frequency of adverse outcomes	An adverse outcome was frequently observed in patients who did not receive OMT, but was infrequently observed in patients who did receive OMT (equivalent to a small number needed to treat)
2a	Systematic review with homogeneity of cohort studies	Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects
2b	Individual cohort study or low-quality randomized controlled trial	Low quality may be indicated by such factors as important differences in baseline characteristics between groups, lack of concealment of treatment allocation, and excessive losses to follow-up
3a	Systematic review with homogeneity of case-control studies	Individual studies should be free of substantial variations in the directions and magnitudes of OMT effects
3b	Individual case-control study	These should be free of substantial evidence of selection bias, information bias, or confounding variables
4	Case series and low-quality cohort and case-control studies	Low quality of cohort and case-control studies may be indicated by such factors as important sources of selection bias, information bias, or confounding variables
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	These generally will have limited empirical data relevant to OMT effects in human populations

Adapted from Straus SE, Richardson WS, Glasziou P, and Haynes RB, Evidence-based medicine. How to practice and teach EBM (3rd ed), 2005.

## Clinical Algorithm(s)

An algorithm titled "Algorithm for OMT LBP decision making" is provided in the original guideline document.

## Scope

### Disease/Condition(s)

Low back pain

### Guideline Category

Management

Treatment

### Clinical Specialty

Family Practice

Internal Medicine

## Intended Users

Health Care Providers

Physicians

Utilization Management

## Guideline Objective(s)

- To assist osteopathic physicians in appropriate utilization of osteopathic manipulative treatment (OMT) for patients with low back pain
- To enable osteopathic physicians, as well as other physicians, other health professionals, and third party payers, to understand the evidence underlying recommendations for appropriate utilization of OMT, which is not detailed in the current sets of guidelines developed by other physicians

## Target Population

Patients with nonspecific low back pain of musculoskeletal origin

Note: Patients with visceral disease conditions that refer pain to the low back are excluded from these guidelines. Other conditions of exclusion are when the following are the identified source of the low back pain: vertebral fracture; vertebral joint dislocation; muscle tears or lacerations; spinal or vertebral joint ligament rupture; inflammation of intervertebral discs, spinal zygapophyseal facets joints, muscles or fascia; skin lacerations; sacroiliitis; ankylosing spondylitis; or masses in or from the low back structures. Exclusion from this guideline does not imply that osteopathic manipulative treatment (OMT) is contraindicated in these conditions.

## Interventions and Practices Considered

Osteopathic manipulative treatment (OMT) for somatic dysfunctions related to low back pain

## Major Outcomes Considered

### Primary Outcomes\*

Pain (as measured by visual analogue scale [VAS], number rating scale [NRS], or the McGill Pain Questionnaire)

Functional status (as measured by the Roland-Morris Disability Questionnaire, Oswestry-Disability Index, or another valid instrument)

\*The point of measurement for both outcomes was the first 3-month interval.

### Secondary Outcome

Any kind of adverse event

## Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

### Evidence Collection

This guideline update process commenced with literature searches that included electronic databases, personal contact with key researchers of osteopathic manipulative treatment (OMT) and low back pain, and internet search engines. In August 2014, a member of the Task Force conducted a literature search using keywords including *back pain*, *low back pain*, *osteopathic manipulative treatment (OMT)*, *osteopathic*, *manual therapy*, and *randomized controlled trials (RCT)* in PubMed, CINAHL, Science Direct, and Springer Link databases from 2003 to 2014. During this search, the systematic review by Franke et al. published in August 2014 (see the "Availability of Companion Documents" field) was discovered and a determination was made to base the revised guidelines on this publication.

Franke et al. searched electronic reference databases Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PEDro, OSTMED.DR, and Osteopathic Web Research using the following search terms: *low back pain*, *back pain*, *lumbopelvic pain*, *dorsalgia*, *osteopathic manipulative treatment*, *OMT*, and *osteopathic medicine*. In addition to the listed databases, the authors conducted searches in an ongoing trial database (metaRegister of Controlled Trials). To enhance their search, Franke et al. tracked citations of identified trials, and manually searched reference lists for other relevant papers.

Franke et al. searched electronic databases, reference lists and personal communications. Their inclusion criteria consisted of randomized clinical trials of adults (>18 years of age) with nonspecific back pain treated by osteopathic physicians or osteopaths who used their clinical judgment as opposed to a standard predetermined protocol. Studies with pregnant and postpartum participants were also included. Studies excluded from the review were those where co-interventions were not performed on both comparison groups; the OMT intervention could not be assigned an effect size; participants had specific back pain from pathology (i.e., fracture, tumor, metastasis, inflammation, infection); or the intervention consisted of a single manual technique.

Also in August 2014, personal communications yielded 2 additional articles by Hensel et al and Licciardone and Aryal published after Franke et al. conducted their systematic review. No other studies were identified. Refer to the original guideline document for information on inclusion of these articles.

## Number of Source Documents

The authors of the systematic review identified 307 studies. Thirty-one were evaluated and 16 were excluded. Of the 15 studies included in the review, 6 were retrieved from Germany, 5 from the United States, 2 from the United Kingdom, and 2 from Italy (see Figure 1 in the systematic review [see the "Availability of Companion Documents" field] for a flowchart of study selection). Two additional studies published after the Franke et al. review were also included.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Levels of Evidence

Strength of Evidence	Type of Study	Comment
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## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Franke et al. reviewed all of the studies using a standardized form, and all mean differences (MD) and standard mean differences (SMD) were calculated with 95% confidence intervals (CIs). Overall effect size was calculated at the 3-month posttreatment follow-up. The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach, as recommended by the updated Cochrane Back Review Group method guidelines, was used to assess quality of evidence.

Franke et al. evaluated the methodological quality of the studies using the Risk of Bias tool of the Cochrane Back Review Group. Studies were scored as "low risk," "high risk," or "unclear," and included assessments of randomization, blinding, baseline comparability between groups, patient compliance, and dropping out. Per the Cochrane Back Review Group, studies received a "low risk" score when a minimum of 6 criteria were met and it was determined that the study had no serious flaws (e.g., a drop-out rate over 50%). Disagreements about the quality of the studies were resolved through discussion and consensus. Franke et al. used Review Manager to analyze the data for the meta-analysis. The authors converted the number rating scale (NRS) and visual analogue scale (VAS) scores from the included studies to a 100-

point scale for the pain measurement, and calculated the MD with 95% CIs for the random effects model.

Franke et al. conducted other noteworthy analyses. The SMD was used in a random effects model to determine functional status. The authors grouped the 1 study examining acute low back pain (LBP) and the 3 studies examining patients with both acute and chronic LBP together for the purpose of their meta-analyses. Overall, they created four groups: (1) acute and chronic LBP; (2) chronic LBP (duration of pain more than 3 months); (3) LBP in pregnant women; and (4) LBP in postpartum women.

Franke et al. also assessed the clinical relevance of each study using the Cochrane Back Review Group recommendations. A small effect was defined as MD less than 10% of the scale and SMD less than 0.5. A medium effect was defined as MD 10% to 20% of the scale and SMD from 0.5 to 0.8. A large effect was defined as MD greater than 20% of the scale and SMD greater than 0.8.

## Methods Used to Formulate the Recommendations

Expert Consensus

### Description of Methods Used to Formulate the Recommendations

These guidelines are based on a systematic review of the literature on osteopathic manipulative treatment (OMT) for patients with low back pain and a meta-analysis of all randomized controlled trials of OMT for patients with low back pain in ambulatory settings. Additionally, they build upon the 2009 American Osteopathic Association (AOA) Clinical Practice Guidelines for Low Back Pain and the 2005 systematic review by Licciardone et al. on which the previous guidelines were based.

The AOA Bureau of Osteopathic Clinical Education and Research convened a Task Force on the Low Back Pain Clinical Practice Guidelines to revise the guidelines. A well rounded, objective perspective is presented. Any view from an osteopathic perspective that is not supported by the scientific literature is stated and clearly identified so the reader is able to discern any potential for bias.

### Rating Scheme for the Strength of the Recommendations

Not applicable

### Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

Internal Peer Review

### Description of Method of Guideline Validation

Guidelines were reviewed by the Bureau of Osteopathic Clinical Education and Research, the American Osteopathic Association (AOA) Board of Trustees, and the AOA House of Delegates.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the recommendation (See "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Potential benefits include, but are not limited to, improved care for patients seeing osteopathic physicians or practitioners for somatic dysfunctions causing low back pain.

### Potential Harms

Harms have not been identified in randomized clinical trials on osteopathic manipulative treatment (OMT) for patients with low back pain. OMT for somatic dysfunction has not demonstrated harm in any clinical trials to date.

## Qualifying Statements

### Qualifying Statements

Limitations of the studies included in these guidelines are the small sample sizes and difference in comparison groups. For Franke et al., the majority of the included studies had relatively small sample sizes, but collectively, there were over 400 participants included in the analysis of chronic and acute pain and for chronic pain. Unfortunately, the separate analysis of low back pain (LBP) in pregnant and postpartum women was collectively a smaller sample (<400 participants), which indicated an imprecision of results and a downgrading of the level of evidence. Also, as Franke et al. alluded to in their article, the control groups included in studies need to be more compatible to the osteopathic manipulative treatment (OMT) intervention groups.

Another limitation of the studies included in the Franke review was the absence of reporting on the exact OMT interventions performed for each patient; only a range of manual techniques for OMT were included. The lack of specific information on the delivery of OMT results in the inability to ascertain the treatment received by different patient groups or to identify the most effective OMT interventions for LBP.

## Implementation of the Guideline

### Description of Implementation Strategy

One of the barriers to application of the recommendations cited by osteopathic physicians has been poor reimbursement for osteopathic manipulative treatment (OMT). However, Medicare has reimbursed osteopathic physicians for this procedure for over 30 years. Many osteopathic physicians apparently do not utilize OMT in clinical practice due to a number of barriers, including time constraints, lack of confidence, loss of skill over time from disuse, and inadequate office space. Some specialists (i.e., pathologists and radiologists) do not use OMT as it is not applicable to their duties within their specialty. The American Osteopathic Association (AOA) believes patients with low back pain should be treated with OMT given the high level of evidence that supports its efficacy. Changes in care when these guidelines are implemented will be determined by physician and patient surveys, billing and coding practice patterns

amongst osteopathic physicians, data gathered from osteopathic physicians via the AOA's Clinical Assessment Program, and other registry data gathering tools currently being developed by researchers.

## Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

## Identifying Information and Availability

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### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2016 Aug

### Guideline Developer(s)

American Osteopathic Association - Professional Association

### Source(s) of Funding

This project was funded by the American Osteopathic Association.

## Guideline Committee

American Osteopathic Association, Bureau of Osteopathic Clinical Education and Research, Task Force on the Low Back Pain Clinical Practice Guidelines

## Composition of Group That Authored the Guideline

*Task Force Members:* Richard J. Snow, DO, MPH (*Chair*); Michael Seffinger, DO; Kendi Hensel, DO, PhD; Rodney Wiseman, DO

## Financial Disclosures/Conflicts of Interest

As the guidelines were developed based on the peer reviewed scientific literature, no conflict of interest is claimed by the developers.

## Guideline Status

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This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the [Journal of the American Osteopathic Association Web site](#) .

## Availability of Companion Documents

The following is available:

Franke H, Franke J-D, Fryer G. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. BMC Musculoskeletal Disorders 2014;15:286. Available from the [BioMed Central Web site](#) .

## Patient Resources

None available

## NGC Status

This summary was completed by ECRI Institute on May 7, 2010. The information was verified by the guideline developer on June 4, 2010. This summary was updated by ECRI Institute on September 9, 2016. The updated information was verified by the guideline developer on October 6, 2016.

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